

QUALITY CONTROL DEPARTMENT
CITALOPRAM HYDROBROMIDE – Ph. Eur.
CERTIFICATE OF ANALYSIS

Commercial batch # : CTH/1210280	Dispatch Qty. : 40.00 Kg
In-house Batch # : 2CTH9/12263	Batch Qty. : 65.30 Kg
Mfg. Date : October- 2012	Retest date : September- 2016
Specification # : QCD/SP/FP/CTH/004-R ₃	Method # : QCD/MH/FP/CTH/004-R ₂

Sl. #.	TESTS	OBSERVATIONS	STANDARD LIMIT
1	Characters - Appearance - Solubility	Almost white crystalline powder Meets the requirement	White or almost white crystalline powder Sparingly soluble in water and in anhydrous ethanol.
2	Identification - Optical rotation - IR absorption spectrophotometry - Test for Bromide	Meets the requirement Meets the requirement Meets the requirement	Sample is to comply with test The IR absorption spectrum of sample should be concordant with that of working standard Should be positive
3	Loss on drying at 105°C for 4 hrs	0.20%	Not more than 0.5%
4	Optical rotation (5% solution in methanol at 20°C)	0.01°	Between -0.10° and + 0.10°
5	Sulphated ash	0.06%	Not more than 0.1%
6	Heavy metals	Less than 20 ppm	Not more than 20ppm
7	Related substances by HPLC Impurities at 230 nm - Impurity - B - Impurity - D - Maximum unspecified impurity - Sum of the impurities (Other than impurity-G) Impurities at 254 nm - Impurity -G	Not detected 0.07% 0.05% 0.12% 0.06%	Not more than 0.15% Not more than 0.2% Not more than 0.10% Not more than 0.5% Not more than 0.15%
8	Assay by Potentiometry (on dried basis)	100.1%	99.0% - 101.5%
9	Additional tests a) Residual solvents by GC-HS - Methanol - Isopropyl Alcohol - Toluene	51 ppm 108 ppm Below detection limit(0.5 ppm)	Not more than 500 ppm Not more than 500 ppm Not more than 100 ppm

Remark : The product complies with above specification +Customer's specification(CSO/506-R₁/12)
Storage condition: Store in airtight containers below 25°C
Note: The values given in the parenthesis limit of detection and disregard of HPLC and respective residual solvents

PREPARED BY : Date : 12/10/12	CHECKED BY : Date : 12/10/12	APPROVED BY : Date : 12/10/12
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A Jubilant Bhartia Company

OUR VALUES



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